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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,329	03/05/2002	Alan A. Winder	41482/205543	9927

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EXAMINER	
SMITH, RUTH S	
ART UNIT	**PAPER NUMBER**
3737	

DATE MAILED: 10/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/980,329	WINDER ET AL.	
	Examiner	Art Unit	
	Ruth S. Smith	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 11-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *20-22* is/are allowed.

6)☒ Claim(s) *11-19,23 and 24* is/are rejected.

7)☒ Claim(s) *1-9* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/25/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 25, 2006 has been entered.

Claim Objections

Claims 1-9,11-19,23,24 are objected to because of the following informalities: In claim 1, line 8, "the ultrasonic source" lacks antecedent basis. In claim 9, it is unclear as to how the capsule set forth differs from the capsule set forth in claim 1. It does not appear that, as disclosed, more than one capsule is used. In claim 11, it is unclear as to whether the delivery/release system provides the functions set forth on lines 12-14. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 11,14-19,23,24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Unger in view of Talish et al ('162), and Ishikawa et al. Unger discloses a method for treating a patient comprising introducing an ultrasound contrast agent into a patient, impinging ultrasound waves in proximity to the treatment area, wherein the ultrasound contrast agent facilitates in lowering the cavitation threshold (see column 10, lines 42-45). The contrast agent is targeted to a specific area within the body and it would have been obvious to one skilled in the art that the targeted area would be the area to be treated. Unger discloses that any type of ultrasound transducer can be used to provide the ultrasound waves. The ultrasound can be provided simultaneously with the MRI. Unger fails to specifically disclose the structure of the ultrasound device for applying the therapeutic ultrasound, the manner in which the contrast agent is released and fails to specifically disclose mounting the ultrasound source to the body. Talish et al disclose an apparatus for applying therapeutic ultrasound to treat areas in a patient. The structure disclosed by Talish includes all the ultrasound elements as set forth in the claims. The ultrasound source is mounted to the patient's body. It would have been obvious to one skilled in the art to have modified Unger such that the therapeutic ultrasound source is mounted to the body to enable simultaneous MRI operation to be more easily performed. Furthermore, it would have been obvious to one skilled in the art to have modified Unger such that the device used to provide the ultrasound is as taught by Talish et al. The modification merely involves the selection of one of many known types of therapeutic ultrasound assemblies. Ishikawa et al disclose a capsule system for delivering "molecules of biological significance" to a patient. The capsule system includes a capsule having a sensor and a material to be delivered. A remote means is used to transmit a signal to the sensor to aid in the release of the material to the patient. It would have been obvious to one skilled in the art to have further modified Unger such that the means for delivering the contrast agent into the patient is as taught by Ishikawa et al. Such a modification

merely involves the substitution of one known type of delivery system for another and allows a more controlled delivery system to be used.

Claims 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Unger in view of Talish et al and Ishikawa et al as applied to claim 11 above, and further in view of Unger et al. Unger et al disclose a delivery system for delivering a material into a patient via microbubbles. The microtubules can be intravenously introduced into the patient using a syringe. Furthermore, the material in the microbubbles is released via the application of energy over time and is therefore considered to be time-released forms of application. It would have been obvious to one skilled in the art to have further modified Unger such that the microbubbles are introduced via an IV using a syringe in a time released manner as disclosed by Unger et al. Such a modification merely involves the selection of a well known means for introduction of a material into a patient.

Claims 11-19,23,24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duarte et al (5,904,659) in view of Vago, Unger, Ishikawa et al, Unger et al and Lang et al. Duarte et al disclose a method of accelerating a healing process using ultrasound. The method involves mounting an ultrasonic source to the patient and impinging ultrasonic waves in proximity to the treatment area where healing is to occur. The SATA set forth in column 4 resides in the range set forth in claim 2. Vago discloses using ultrasound to promote wound healing. Vago discloses that the ultrasound produces stable cavitation to promote healing. Therefore, it appears that Duarte et al inherently involves the production of cavitation. Unger discloses a method for treating a patient comprising introducing an ultrasound contrast agent into a patient, impinging ultrasound waves in proximity to the treatment area, wherein the ultrasound contrast agent facilitates in lowering the cavitation threshold (see column 10, lines 42-45). The contrast agent is targeted to a specific area within the body and it would have been obvious to one skilled in the art that the targeted area would be the area to be treated in order to ensure treatment of the desired area. The intensity of the ultrasound is maintained in the range as set forth in claim 2 (see column 10, lines 46-48). The

contrast agent is comprised of microbubbles having a radius in the range set forth in claims 3,21 (see column 15, lines 17-19). With regard to claim 4, resonant bubble frequency as set forth is inherent in the operating parameters of the system and the microbubbles used. Unger discloses that any type of ultrasound transducer can be used to provide the ultrasound waves. It would have been obvious to one skilled in the art to have modified Duarte et al such that the ultrasound produces cavitation which promotes wound healing as disclosed by Vago and to have used a contrast agent in order to lower the cavitation threshold as disclosed by Unger in order to prevent harming the patient. With regard to claim 5, Duarte et al disclose a carrier frequency and intensity selected by taking into account various factors. In the absence of any showing of unexpected results, the frequency of the ultrasonic waves could be determined by one skilled in the art without undue experimentation based upon the factors set forth by Duarte et al in column 4. With regard to claim 6, Unger fails to specifically disclose the treatment time set forth. Unger discloses that the ultrasound can be applied until the desired effect is achieved. In the absence of any showing of criticality, the specific time that the treatment lasts would have been obvious to one skilled in the art and could be determined without undue experimentation as the time it takes for the desired effect to be achieved. The kit is inherent in the use of the method. Ishikawa et al disclose a capsule system for delivering "molecules of biological significance" to a patient. The capsule system includes a capsule having a sensor and a material to be delivered. A remote means is used to transmit a signal to the sensor to aid in the release of the material to the patient. It would have been obvious to one skilled in the art to have further modified Unger such that the means for delivering the contrast agent into the patient is as taught by Ishikawa et al. Such a modification merely involves the substitution of one known type of delivery system for another and allows a more controlled delivery system to be used. Unger et al disclose a delivery system for delivering a material into a patient via microbubbles. The microbubbles can be intravenously introduced into the patient using a syringe. Furthermore, the material in the microbubbles is released via the application of energy over time and is therefore considered to be time-released forms of application. In the absence of any showing of

criticality, the manner in which the contrast agent is introduced into the patient would have been a matter of design choice of known equivalents in the art such as those disclosed by Unger et al. It is a well known expedient in the art to provide medical equipment for a procedure in the form of a kit, as shown by Lang et al, so an to simplify the ability to carry out the procedure by providing all required medical elements for such is a self-contained package. Therefore, it would have been obvious to one skilled in the art to have further modified Duarte et al such that the structural elements necessary to carry out the method are provided in kit form.

Allowable Subject Matter

Claims 20-22 are allowable over the prior art of record.

Claim 1-9 would be allowable if rewritten to overcome the objections set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments filed September 25, 2006 have been fully considered but they are not persuasive. With respect to claim 11, it should be noted that the claim fails to positively set forth a capsule having a piezoelectric sensor capable of receiving an acoustic signal instructing the capsule to release a portion of the contrast agent.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth S. Smith whose telephone number is 571-272-4745. The examiner can normally be reached on M-F 7:30 AM-4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ruth S. Smith
Primary Examiner
Art Unit 3737

RSS